DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ROCHE DIAGNOSTICS
NATHAN CARRINGTON
DIRECTOR OF REGULATORY AFFAIRS
9115 HAGUE ROAD
INDIANAPOLIS MD 46250

August 29, 2014

Re: K133741
Trade/Device Name: ACCU-CHEK Performa Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: July 25, 2014
Received: July 29, 2014

Dear Mr. Nathan Carrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
k133741

Device Name
ACCU-CHEK Performa Blood Glucose Monitoring System

Indications for Use (Describe)
The ACCU-CHEK Performa Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in venous whole blood or fresh capillary whole blood from the fingertips. The ACCU-CHEK Performa Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid in monitoring the effectiveness of glucose control. This system should only be used with single-use, auto-disabling lancing devices.

The ACCU-CHEK Performa Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. This system is also not for neonatal use.

The ACCU-CHEK Performa test strips are for use with the ACCU-CHEK Performa meter to quantitatively measure glucose (sugar) in venous whole blood or fresh capillary whole blood samples from the fingertips.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter Name, Address, Contact

Roche Diagnostic Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-4793
Contact Person: Nathan Carrington
Date Prepared: August 26, 2014

2. Device Name

Proprietary names: ACCU-CHEK Performa System
ACCU-CHEK Performa Test Strip
ACCU-CHEK Performa Meter

Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345); Class II

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase

3. Predicate Device

ACCU-CHEK Inform II System (k121679), concurrence received on 11 October 2012.

The ACCU-CHEK Inform II blood glucose monitoring system is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings.

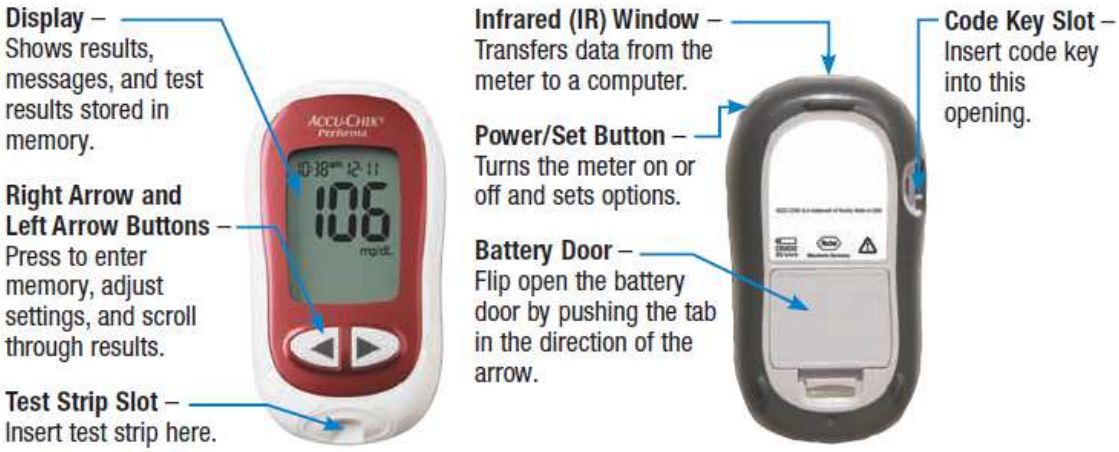
4. Device Description

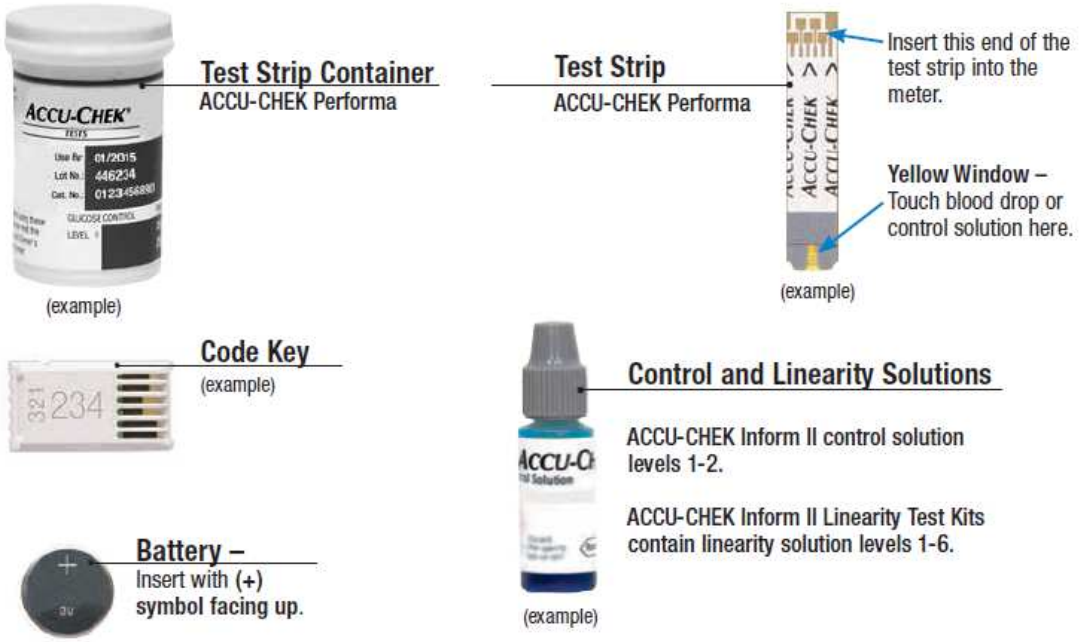
The ACCU-CHEK Performa System consists of the following:

- ACCU-CHEK Performa Meter
- ACCU-CHEK Performa test strips
- ACCU-CHEK Inform II control solutions (k121679)
- ACCU-CHEK Inform II Linearity Test Kit (k121679)

The ACCU-CHEK Performa blood glucose monitoring system is a blood glucose monitoring system that makes use of the ACCU-CHEK Performa test strips, the ACCU-CHEK Performa meter, the ACCU-CHEK Inform II Control Solutions (cleared under k121679), and the ACCU-CHEK Inform II Linearity Test Kit (cleared under k121679). This system is a multi-patient use blood glucose monitoring system intended to be used in a professional environment to quantitatively measure glucose in venous whole blood and fresh capillary whole blood samples drawn from the fingertips.

The components of the ACCU-CHEK Performa blood glucose monitoring system are shown below:





5. Intended Use

The ACCU-CHEK Performa Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in venous whole blood or fresh capillary whole blood from the fingertips. The ACCU-CHEK Performa Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid in monitoring the effectiveness of glucose control. This system should only be used with single-use, auto-disabling lancing devices.

The ACCU-CHEK Performa Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. This system is also not for neonatal use.

The ACCU-CHEK Performa test strips are for use with the ACCU-CHEK Performa meter to quantitatively measure glucose (sugar) in venous whole blood or fresh capillary whole blood samples from the fingertips.

6. Substantial Equivalence

The ACCU-CHEK Performa System is substantially equivalent to the ACCU-CHEK Inform II System. Below is a table that provides a comparison between the ACCU-CHEK Performa System and its predicate device.

Similarities Table

System Feature/Claim	Detail
Test Strip	**Same**: The Performa and Inform II test strips are identical.
Test Strip Production Processes and Lot-Release Criteria	**Same**: The Performa and Inform II test strips are identical.
Meter firmware for measurement sequence and blood glucose calculation algorithm	**Same**: The fundamental scientific technology for the measurement of blood glucose has not changed from the predicate.
Meter Analog and Digital device integrated circuits used for glucose measurement	**Same**
Meter measurement engine microprocessor	**Same**
Underdose detection and system fail-safes	**Same**
Meter production site and assembly methodology	**Same**
Meter production test and calibration methods	**Same**
Integrity Check for Strip	**Same**: Early in the measurement sequence, the meter measures the resistance of the gold on the un-dosed strip to assure that it has been properly inserted and that the quality is not compromised. The meter measures the background conductivity and electrical current prior to dosing to assure that the reagent quality is not compromised or that the strip was not prematurely dosed.

Similarities Table (continued)

System Feature/Claim	ACCU-CHEK Performa Blood Glucose Monitoring System	ACCU-CHEK Inform II Blood Glucose Monitoring System Predicate (k121679)
Indications for Use	Quantitative measurement of glucose (sugar) in venous whole blood or fresh capillary whole blood samples.	Quantitative measurement of glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples.
Test Principle	Amperometric Detection	Amperometric Detection
Enzyme	Mut. Q-GDH	Mut. Q-GDH
Sample Hematocrit	10 to 65%	10 to 65%
Maximum Altitude	10,000 feet	10,000 feet
Sample Volume	0.6 µL	0.6 µL
Test Time	5 seconds	5 seconds
Operating Temperature and Relative Humidity	16 to 35ºC (61 to 95ºF) 10 to 80% r.h.	16 to 35ºC (61 to 95ºF) 10-80% r.h.
Coding	Lot-specific blood glucose measurement parameters are programmed into ROM code key	Lot-specific blood glucose measurement parameters are programmed into ROM key
Precision	For response targets below 75 mg/dL, the SD is ≤ 5.0 mg/dL, and for response targets ≥ 75 mg/dL, the CV is ≤ 5.0%.	For response targets below 75 mg/dL, the SD is ≤ 5.0 mg/dL, and for response targets ≥ 75 mg/dL, the CV is ≤ 5.0%.
Double Dosing	No	No
Alternate Site Testing	No	No

Similarities Table (continued)

System Feature/Claim	ACCU-CHEK Performa Blood Glucose Monitoring System	ACCU-CHEK Inform II Blood Glucose Monitoring System Predicate (k121679)
Closed and Open Vial Shelf Life Stability	18 months	18 months
Control Solutions	Aqueous, 2 levels, uses ACCU-CHEK Inform II Control Solutions	Aqueous, 2 levels, uses ACCU-CHEK Infrom II Control Solutions
Linearity Kit	Aqueous, 6 levels, uses ACCU-CHEK Inform II Linearity Test Kit	Aqueous, 6 levels, uses ACCU-CHEK Inform II Linearity Test Kit
Primary Packaging	Standard flip top vial	Standard flip top vial
Limitations of Procedure	Galactose >15 mg/dL will cause overestimation of blood glucose results.	Galactose >15 mg/dL will cause overestimation of blood glucose results.
	Lipemic Samples >1800 mg/dL	Lipemic Samples >1800 mg/dL
	Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results	Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results

Differences Table

System Feature/Claim	ACCU-CHEK Performa Blood Glucose Monitoring System	ACCU-CHEK Inform II Blood Glucose Monitoring System Predicate (k121679)
Meter Physical Appearance Including Size and Weight	3.7 in x 2.1 in x 0.9 in (LWH), 0.14 lbs 93 mm x 52 mm x 22 mm (LWH), 62 g	7.60 in x 3.74 in x 1.73 in (LWH), 0.83 lbs 193 mm x 95 mm x 44 mm (LWH), 376 g
Ergonomics of User Interface	Two buttons located on the face of the meter; power button on top edge of the meter.	Power button located on the face of the meter; touch-sensitive display.
Code Key Port	Code key inserts directly into code key slot in meter.	Code key inserts into code key reader which transfers data to meter via IR communication
Battery	One 3-volt lithium type CR2032 coin cell	3.7 V rechargeable battery pack (lithium technology)
Data Management Features	Simplified for basic blood glucose testing.	Additional firmware for added features, such as the tracking of patient information
Bar Code Scanner	None	Present
Transmission of Retrospective Data to External Devices	None	Wirelessly to WLAN through RF communication or to docking station base unit through IR data port
Measuring Range	20 – 600 mg/dL	10 – 600 mg/dL

7. Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Performa System demonstrated that the device meets the performance requirements for its intended use. The data demonstrate that the system is substantially equivalent to the predicate device.

Below is the method comparison data for the system:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
17/19 (89.5%)	18/19 (94.7%)	19/19 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20 %
50/86 (58.1%)	78/86 (90.7%)	84/86 (97.7%)	85/86 (98.8%)

Below is the repeatability (wtihin lot) precision for the system:

Blood	**1**	**2**	**3**	**4**	**5**
N	100	100	100	100	100
Mean [mg/dL]	37.1	81.1	134.6	216.2	345.3
SD [mg/dL]	1.7	2.7	4.4	7.9	10.2
CV [%]	4.7	3.4	3.3	3.6	3.0

Below is the reproducibility (intermediate or day-to-day) precision for the system:

Control solutions	**Low**	**Mid**	**High**
N	100	100	100
Mean [mg/dL]	45.8	118.8	310.8
SD [mg/dL]	1.5	2.7	6.6
CV [%]	3.2	2.3	2.1